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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/735,153	Applicant(s) BALLERSTADT ET AL.	
	Examiner Melanie Yu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,71-80 and 102-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31,71-80 and 102-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and arguments filed 10 August 2005 have been entered. Claims 1, 2, 4, 5, 12-14, 16, 18, 29-30, 71-72, 74-75, 78-80, 102, 104 and 115-116 are currently amended. Claims 118-123 are new. Claims 32-70 and 81-101 are cancelled. Claims 1-31, 71-80 and 102-123 are currently pending in this application.

Withdrawn Rejections

2. Previous rejections under 35 USC 102(b) have been withdrawn in light of applicant's amendment. Previous rejections under 35 USC 112, second paragraph have been withdrawn.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 80 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "a first wavelength" in line 4 of the claim and "a second wavelength in line 5 of the claim. It is unclear whether these first and second wavelengths are intended to be the same first and second wavelengths of claim 71 or if first and second wavelengths other than those recited in claim 71 exist.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-8, 11, 12, 15-21, 23, 24, 27, 28, 31, 71, 72, 76, 77, 79, 80, 102-107, 109-110, 113-114 and 117are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al (US 2002/0197724).

With respect to claims 1, 2, 4, 6, 7, 11, 15, 71, Chick et al. teach an analyte sensing device for sensing a concentration of analyte in a fluid and capable of being implanted within subcutaneous tissue of an animal body (col. 17, lines 39-43), comprising: a housing including a hollow dialysis fiber (col. 12, lines 9-13; col. 13, line 66-col. 14, line 3) and the housing comprising a semipermeable membrane (col. 5, lines 57-58); an analyte sensing component disposed within the housing and including: a first radiation converting component that is capable of converting radiation of a first wavelength to radiation having at least one different wavelength, wherein the efficiency of conversion is dependent on the concentration of analyte within the housing (converting component is the donor component; col. 3, lines 9-13; col. 5, lines 57-67); an analyte specific binding ligand being lectin (col. 2, line 66-col. 3, line 2; col. 10, line 15) in close proximity to a radiation absorbing component that is sufficient to alter the efficiency of the conversion of the radiation of the first wavelength by the first radiation converting component (col. 5, lines 63-65); and a macroporous matrix wherein the analyte-specific binding ligand is attached to the surface of the macroporous matrix (col. 5, lines 57-67); a radiation providing unit to provide radiation at the first wavelength (col. 16, lines 32-34; col. 17, lines 22-25); and a radiation detecting unit to detect the radiation of one different wavelength and to output data which is representative of the intensity of the radiation emitted by the first radiation converting component (col. 16, lines 35-36). Chick et al. fail to teach a second radiation converting component independent of the concentration of analyte.

Noronha et al teach a housing of a hollow dialysis fiber (par. 59) comprising first and second radiation converting component wherein the first radiation component is a reporter fluorophore that is associated with a concentration of glucose in a sample (par. 85-86) and the second radiation converting component is a reference fluorophore that converts radiation of a second wavelength to at least one wavelength that is different from the second wavelength by receiving radiation at a second wavelength and emitting radiation having at least one wavelength that is different from the second wavelength (fluorophore is used, and absorbs and emits radiation at different wavelengths, par. 154), wherein an efficiency of conversion of the radiation of the second wavelength by the second radiation converting component is independent of the concentration of glucose (fluorescence emitted by second fluorophore does not overlap the absorption spectrum of the reporter species and is independent of the concentration of the absorbing species, wherein the concentration of the absorbing species is dependent on the concentration of glucose; reference fluorophores are independent of analyte concentrations; par. 84-87) and a radiation detecting unit that detects radiation emitted by the first and second radiation converting components (reference fluorophore and fluorescent moiety emit at different wavelengths, par. 85; therefore both wavelengths must be detected by detection unit to determine concentration, par. 111-113), in order to provide an internal referencing system to correct for orientation of position of the matrix relative to the sensing means and to cancel out confounding changes in sensitivity of the sensing means.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al., a radiation converting component wherein the efficiency of conversion is independent of the concentration of analyte as taught by

Noronha et al., in order to provide an internal referencing system to correct for background fluorescent signals and cancel out changes in fluorescence intensity.

With respect to claims 3-5, Noronha et al. teach a semi-permeable or permeable membrane (permeable to glucose, and is therefore semi-permeable to the entire sample, par. 59) comprised of a cellulose acetate material (par. 67).

Regarding claims 8 and 102, Chick et al. teach an analyte sensing component further including a radiation absorbing component having a proximity to the analyte-specific binding ligand that is sufficient to alter the efficiency of the conversion of the radiation of the first wavelength by the first radiation converting component (acceptor component is an absorbing component; col. 3, lines 9-13; col. 5, lines 57-67).

With respect to claim 12, Chick et al. teach an analyte sensing component further comprising an analyte-analogue capable of being bound by an analyte-specific binding ligand (ligand labeled with acceptor and donor; col. 5, lines 57-67).

Regarding claim 15, Noronha et al. teach the device capable of being implanted within the subcutaneous tissue of an animal body (par. 110).

With respect to claims 16-21, 23, 24, 103-107 and 109-110, Chick et al. teach an analyte sensing component further comprising: an analyte analogue (analogue, col. 5, lines 57-67) of dextran (col. 14, lines 55-57), a glycosylated protein (col. 10, lines 13-17) or a chain of glucose residues (col. 10, line 62); a radiation absorbing component having a proximity to the analyte specific binding ligand that is sufficient to alter the efficiency of the conversion of the radiation of the first wavelength by the first radiation converting component when the analyte analogue is bound by the analyte-specific binding ligand (first radiation absorbing component attached to

analogue; col. 5, lines 57-67); and wherein the first radiation converting component is attached to the analyte analogue and the analyte specific binding ligand is capable of binding to the analyte and the analyte-analogue (col. 5, lines 57-67). Chick et al. further teach a housing comprising a semi-permeable membrane, which allows analyte to move into or out of the housing, but does not allow analyte-sensing components to move out of the housing (col. 5, lines 57-58). Chick et al. also teach the efficiency of conversion of radiation at a first wavelength to radiation having at least one different wavelength by the first radiation converting component is decreased when the analyte-analogue is bound by the analyte specific binding ligand (the radius, R, decreases when analyte-analogue is bound to analyte ligand, and therefore the efficiency of conversion is decreased; col. 8, lines 48-65). Chick et al. teach the ligand being a lectin (col. 10, line 15) of Concanavalin A (col. 8, lines 50-54).

With respect to claims 27, 28, 31, 113-114 and 117, Chick et al. teach a radiation absorbing component covalently bound to the analyte-specific binding ligand (acceptor component; col. 10, lines 60-63), and wherein the radiation absorbing component (acceptor component) is attached to the surface of the macroporous matrix (col. 5, lines 57-67). Chick et al. also teaches the analyte being glucose (col. 9, lines 50-54).

Regarding claims 72 and 77, Chick et al. teach an analysis unit coupled to the radiation detecting unit to determine the concentration of analyte within the housing (col. 14, lines 6-11) and the radiation providing unit disposed adjacent to the housing (radiation providing unit is provided transdermally which is adjacent to the sensing system; col. 16, lines 32-36). Noronha et al. teach that the concentration of analyte in the housing is representative of the intensity of the radiation emitted by the first and second radiation converting components (par. 84-86) and

therefore an analysis unit of Noronha et al. would be capable of determining the concentration based on the intensity of radiation emitted by the first and second radiation converting components.

With respect to claim 76, Noronha et al. teach the radiation detecting unit being a CCD array (par. 134).

With respect to claim 79, Noronha et al. teach the analyte sensing system further including an analysis unit coupled to the radiation detecting unit to determine the concentration of the analyte inside the housing, to determine the concentration of analyte inside the housing using the data output by the radiation detecting unit (output reading device, par. 113).

Regarding claim 80, Chick et al. in view of Noronha et al. do not specifically teach the determination of the concentration of the analyte by the analysis unit including conditioning data output and computing the ratio of intensity. However, claim 80 is drawn to a product and the recited limitations are drawn to a method of using and fails to recite further structural limitations required for the analyte sensing system to provide a method of determination. Therefore since Chick et al. in view of Noronha et al. teach the required structural limitations of claim 80, the invention of Chick et al. in view of Noronha et al. is capable of performing the method of detection as recited.

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al. (US 2002/0197724) and further in view of Jordan (US 4,450,104).

Chick et al. in view of Noronha et al., as applied to claims 1, 23, 24 and 31, teach an analyte sensing device for sensing a concentration of analyte in a fluid with an analyte being

glucose and the ligand including a lectin of Concanavalin A, but fail to teach the matrix comprising agarose beads.

Jordan teaches a macroporous matrix including agarose beads comprising lectin (col. 3, lines 21-31), in order to determine ligand binding on the lectin-agarose beads.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha, a matrix comprising agarose beads as taught by Jordan, in order to provide immobilized lectin ligands which bind rapidly, reversibly and are of high affinity.

2. Claims 13, 29, 78 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Noronha et al. (US 2002/0197724), as applied to claims 1, 16, 71 and 102, and further in view of Chagovetz (US 2002/0197611).

Chick et al. in view of Noronha et al., as applied to claims 1, 16, 71 and 102, teach an analyte sensing device comprising a first and second radiation converting component, but fail to teach a third radiation converting component.

Chagovetz teach a first radiation converting component (dependent on concentration of a first analyte, par. 26) and a third radiation converting component (dependent on concentration of a second analyte, par. 26) to convert radiation of a third wavelength to at least one wavelength that is different from the third wavelength, wherein an efficiency of conversion of the radiation of the third wavelength by the third radiation converting component is dependent on the concentration of the analyte in the housing (detects concentration of an analyte different from the first analyte, par. 26; FRET relationship converts radiation of a third wavelength into one wavelength that is different, par. 5, 11), in order to identify two or more variants simultaneously.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha et al., a third radiation converting component as taught by Chagovetz et al., in order to provide increased flexibility of the device by detecting multiple analyte within a sample.

5. Claims 22, 26, 73-75, 108 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al. (US 2002/0197724) and further in view of Djaballah et al. (US 2003/0059811).

Chick et al. in view of Noronha et al., as applied to claims 1, 16, 71 and 102, teach a device comprising a radiation converting component and a radiation absorbing component, but fail to teach the specific radiation converting and absorbing components.

Djaballah et al. teach a radiation converting component being Alexa647 (par. 0113) and a radiation absorbing component being QSY21 (par. 0115), in order to absorb light and transfer excitation energy causing fluorescence.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha et al., radiation absorbing and converting components as taught by Djaballah et al., in order to provide more sensitive detection methods that can be configured for high throughput assays for ligands.

Regarding claims 73-75, Djaballah et al. teach a radiation detecting unit including a plurality of radiation detecting devices wherein each device is capable of detecting a wavelength-specific portion of radiation (par. 0254). Djaballah et al. also teach a first radiation converting component capable of converting radiation of the first wavelength to radiation having a plurality of wavelengths wherein the efficiency of conversion is dependent on the concentration of the

analyte inside the housing; and the radiation detecting unit including a plurality of radiation detecting devices wherein each device is capable of detecting radiation within at least one of the plurality of wavelengths (par. 0254).

3. Claim 25 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al (US 2002/0197724) and further in view of Cosma (US 6,150,123).

Chick et al. in view of Noronha et al., as applied to claims 1, 16, 23, 102 and 109, teach a device comprising a binding ligand of a lectin, but fail to teach the lectin being *Lens culinaris* lectin.

Cosma teaches *Lens culinaris* lectin (col. 6, lines 51-55) in order to bind α-D-glucose and α-D-mannose.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha et al., a ligand of *Lens culinaris* lectin to bind glucose as taught by Cosma, in order to provide a ligand that specifically binds glucose and retains its binding capacity in the presence of non-ionic detergents.

4. Claim 30, 116 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al. (US 2002/0197724), as applied to claims 27, 71 and 115, further in view of Lakowicz et al. (US 2003/0228682).

Chick et al. in view of Noronha et al., as applied claims 29, 71 and 115, teach a device comprising a second radiation converting component, wherein the component can be a rhodamine dye (Noronha et al., par. 46, although rhodamine is spelled rhodatine in paragraph 46,

it is acknowledged as a spelling error because rhodatine is not a dye and rhodamine is a known xanthene fluorescent dye).

Lakowicz et al. teach a dye of rhodamine 800 (par. 0108), which is the same as LD800 (see US 5,610,932; col. 12, lines 66-67), in order to provide a fluorophore that emits electromagnetic energy at a certain wavelength.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha et al., a rhodamine 800 dye as the second radiation converting component as taught by Lakowicz et al., in order to provide a reference fluorophore that does not interfere with the reporter fluorophore and increases the radiative decay rate of weakly fluorescing species.

5. Claims 118, 120 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. in view of Noronha et al., as applied to claims 1, 102 and 122, further in view of Ault-Riche et al. (US 2004/0209282).

Chick et al. in view of Noronha et al., as applied to claims 1, 102 and 122, teach an analyte sensing device comprising a second radiation converting component, but fail to teach the second radiation converting component being TransFluoSpheres.

Ault-Riche et al. teach a radiation converting component of TransFluoSpheres (par. 605), in order to provide an effective tracer of cell morphology.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the second radiation converting component device of Chick et al. in view of Noronha et al., TransFluoSpheres as taught by Ault-Riche et al., in order to provide

a radiation converting component that is capable of introduction into a biological sample as well as long-term retention in the sample.

Claims 14, 119 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (US 6,040,194) in view of Noronha et al. (US 2002/0197724), as applied to claims 1, 71 and 102, and further in view of Mathies et al. (US 5,654,419).

Chick et al. in view of Noronha et al., as applied to claims 1, 71 and 102, teach a device comprising a first and second radiation converting wavelength, but fail to specifically state that the first and second radiation converting components convert radiation of a first and second wavelength that is the same.

Mathies et al. teach two radiation converting components having the same first and second wavelength to activate the components, but emit at detectable different wavelengths (col. 1, line 66-col. 2, line 5; FAM-4-ROX and FAM-3-ROX, Fig. 6; col. 6, lines 7-17), in order to provide efficient energy transfer.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Chick et al. in view of Noronha et al., first and second components with the same first and second wavelengths as taught by Mathies et al., in order to provide a device wherein the components are excited in the visible range and can be emitted in a different range of wavelengths.

Response to Arguments

6. Applicant's arguments with respect to claims 1-31, 71-80 and 102-123 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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